UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC.,	
Plaintiff,	
v.	
F. HOFFMANN-LA ROCHE LTD ROCHE DIAGNOSTICS GmbH and HOFFMANN-LA ROCHE INC.	CIVIL ACTION No.: 05-CV-12237WGY *Leave to file Granted on August 30, 2007*
Defendants.	

DEFENDANTS' REPLY MEMORANDUM OF LAW IN SUPPORT OF ROCHE'S MOTION *IN LIMINE* TO PRECLUDE AMGEN INC. FROM CONTRADICTING ARGUMENTS IT MADE IN PRIOR ADMINISTRATIVE AND JUDICIAL PROCEEDINGS

I. INTRODUCTION

Defendants F. Hoffmann-La Roche LTD, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche") submit this memorandum of law in further support of their Motion *in Limine* to Preclude Amgen Inc. From Contradicting Arguments it Made in Prior Administrative and Judicial Proceedings and to reply to Amgen's lengthy yet irrelevant opposition. Amgen's opposition is a thinly-veiled attempt to distract the Court's attention from the relevant facts and legal issues surrounding Roche's Motion. Recognizing that it has repeatedly presented contradictory arguments in securing favorable judgments in prior proceedings, Amgen treats Roche's motion as one for summary judgment when, in reality, Roche moves this Court to bind Amgen to the standards of integrity the judicial system deserves by precluding it from playing fast and loose with the judicial and administrative systems.

II. ARGUMENT

As Roche explained in its opening memorandum of law (D.I. 802), "[j]udicial estoppel should be employed when a litigant is 'playing fast and loose with the courts'" by "asserting a position in one legal proceeding which is contrary to a position it has already asserted in another." *Patriot Cinemas, Inc. v. Gen. Cinemas Corp.*, 834 F.2d 208, 212 (1st Cir. 1987). Moreover, "it is the court's acceptance of the party's argument, not the benefit flowing from the acceptance, that primarily implicates judicial integrity." *Alternative Sys. Concepts, Inc. v. Synopsys, Inc.*, 374 F.3d 23, 33 (1st Cir. 2004). The evidence shows that this case is the perfect candidate for applying judicial estoppel.

A. Amgen Repeatedly Maintained In The '097 Interference That Every Aspect Of Its "Invention" Beyond The EPO Gene Was Non-Inventive

In its opening memorandum of law, Roche explained events in the prosecution of the patents-in-suit and the related interferences that lead to the clear conclusion that Amgen repeatedly represented to the Board of Patent Appeals and Interferences that the sole novel feature of Dr. Lin's "invention" was the EPO DNA sequence and, accordingly, Amgen should be estopped from offering contradictory arguments in the pending litigation. In opposition, Amgen presents a lengthy history of the *Fritsch v. Lin* Interferences, though the majority of Amgen's history is irrelevant to Roche's motion.

The only relevant facts are that Amgen repeatedly maintained during the 102,097 Interference that the counts of the '096 and '097 were merely part of the same overall invention, such that the Board's rulings in one Interference count would necessarily resolve disputes on the other count. (*See* D.I. 802 at 1-5; D.I. 803 Ex. 3 at 3, 9; D.I. Ex. 4 at 25-26, 57-58). As a result, Amgen persuaded the Board to "agree with Lin" that there is "no evidence that the work done at Amgen relating to the expression of the EPO gene in mammalian host cells and isolation of the

resulting glycoprotein product involved anything other than the exercise of ordinary skill by practitioners in that field" and the Board adopted Lin's position that isolation of the EPO gene was the essential inventive component of Lin's "inventions." *Fritsch v. Lin*, 21 U.S.P.Q.2d 1737, 1738-39 (B.P.A.I. 1991).

Despite these clear, unambiguous statements, Amgen argues that its prior positions are consistent with its arguments in this litigation. In support, Amgen detracts from the real issues by highlighting isolated instances where it argued that its inventions were not obvious under §103, which is completely irrelevant to whether the resulting '868 process claims are patentable over the original Lin '008 patent. To the extent the Board adopted any of Amgen's arguments pertaining to obviousness, it was in relation to the obviousness of isolating the EPO gene, and not the process for producing the EPO polypeptide or the resulting *in vivo* biologically active polypeptide in the context of obviousness-type double patenting. Indeed, even Amgen acknowledges that "[t]he 'obviousness' section of the PTO's decision focuses on (and rejects) Fritsch's flawed assertion that Lin's claims are obvious under 35 U.S.C. § 103 because, according to Fritsch, it was "obvious to try" to isolate the EPO gene in light of prior art such as the Toole et al reference." (D.I. 867 at 9). Instead, the Board accepted Amgen's continuous arguments that the process and resulting polypeptide were routine and non-inventive given the DNA sequence for EPO, and it is precisely these arguments that Amgen should be precluded from contradicting.

The fact that Examiner Schain stated that the "subject matter of the three interferences is deemed to be patentably distinct" (D.I. 867 at 3) is wholly irrelevant to the question of judicial estoppel. That statement was made long ***before*** the Board ever heard Lin's arguments and rendered its decision in the '097 Interference. Accordingly, the fact that Examiner Schain

preliminarily deemed the subject matter to be distinct has no bearing on the Board's subsequent findings and its reliance on Amgen's later assertions that the two applications claimed "different manifestations of the same invention." Similarly, the fact that the PTO issued the '868 patent without a terminal disclaimer over the '008 patent is irrelevant to the question of judicial estoppel based on contradictory statements made to the Interference Board. (*See* D.I. 867 at 14). Amgen did not explain to the Examiner that it had told the Interference Board that the "the isolated DNA sequence is the novel feature of the process claims" or that the process claims are the "same invention" as the original '008 patent.

As Roche explained in its opening brief, Amgen's attempt to attribute its Interference arguments to Fritsch is devoid of merit and irrelevant. Amgen argues that the "different manifestations of the same invention" language was Fritsch's and not Lin's, pointing to an opposition filed in 1989 (D.I. 868 Ex. E at 149) -- over two years ***before*** Amgen filed its brief and the Board made its findings.[1] However, Amgen subsequently abandoned its initial position in favor of the arguments set forth in its later, substantive briefs that were adopted by the Board. Indeed, Amgen ignores the fact that this statement admitting that the process claims are the "same invention" appeared in Amgen's brief, under the heading "Summary of ***Lin's*** Position", and that Amgen stated that the language was "acknowledged by Fritsch," meaning Fritsch agreed with Amgen's position. (D.I. 803 Ex. 4 at 25-26 (emphasis added)). Amgen also conveniently glosses over the fact that it abandoned its initial position at the Board to exploit the favorable

[1] Interestingly, the Board decided to keep the '096 Interference (relating to the '008 patent) and the '097 Interference (concerning the application that led to the '868 patent) as separate interferences not because the counts represented patentably distinct inventions as Amgen contends but, rather, because "there is no provision in the new rules of practice for 'combining' interferences." (D.I. 868 Ex. F at 5). After this ruling, Amgen changed its position.

inventorship decision in *Amgen v. Chugai*. And plainly Amgen has not -- and cannot -- shift the blame to Fritsch for its plain statement that "the isolated DNA sequence is ***the*** novel feature of the process claims." Amgen's attempt to mislead the Court by ignoring the overwhelming weight of the evidence on this issue must fail.

Even if, however, these arguments originated with Fritsch, the Board understood this to be Amgen's argument, and Amgen was duty-bound to correct the Board if it misunderstood Amgen's position. (D.I. 803 Ex. 5). Accordingly, even if Amgen initially opposed combining the interferences, and even if Fritsch was the initial party to use the "different manifestations of the same invention language," Amgen subsequently adopted the argument explicitly, used the argument and similar statements to its benefit, and succeeded in winning the Interferences based on its arguments. Therefore, Amgen should be precluded from now offering entirely contradictory positions.

B. Amgen's Actions In Foreign Proceedings Judicially Estop Amgen From Offering Contradictory Arguments And Support Roche's Arguments With Respect To The Interference

As Roche explained in its opening brief, Amgen's arguments in foreign proceedings not only provide an independent basis for applying judicial estoppel, but also corroborate the fact that Amgen was not merely reciting Fritsch's arguments in the '097 Interference. The evidence is clear that these were consistent Amgen arguments, made repeatedly in different contexts. Amgen's attempt to detract from the preclusive effect of foreign Amgen litigations by treating Roche's motion as one for summary judgment is baseless and Amgen should not be heard to say that it did not truly assert that the only inventive feature of its "inventions" was the isolation of the EPO gene.

Amgen ignores the clear principle of law, discussed in Roche's opening memorandum (D.I. 802 at 9-10) that contradictory arguments made in prior foreign judicial proceedings can give rise to judicial estoppel in a United States litigation. *See A.I. Trade Finance, Inc. v. Centro Internationale Handelsbank AG*, 926 F. Supp. 378, 388-90 (S.D.N.Y. 1996); *see also Hyatt Int'l Corp. v. Coco*, 302 F.3d 707, 717 (7th Cir. 2002).

Moreover, despite Amgen's argument, (D.I. 867 at 15), Roche need not show that the claims of the foreign patents are sufficiently similar to those of the patents-in-suit for judicial estoppel to apply. As noted, Roche is not moving for an order that the claims of the patents-in-suit are invalid for obviousness-type double patenting: that will happen after the evidence is heard at trial. Here, Roche merely seeks an order precluding Amgen from directly contradicting arguments made in securing favorable judgments in prior proceedings. Accordingly, the similarity of the claims and the particular claims at issue are irrelevant to the pending motion. In any event, the claims of the patents-in-suit are indeed substantially similar to those litigated in the foreign proceedings.

Similarly, Amgen's attempt to distinguish its arguments made in the '678 Opposition Proceedings completely fails. Amgen does not dispute that it argued in the foreign proceeding that "the particular type of glycosylation linkages was simply a result of the type of host cell used to produce the recombinant erythropoietin." (D.I. 803 Ex. 9). Nor does Amgen dispute that the foreign court accepted Amgen's assertion. Accordingly, because Amgen's current position -- that the particular glycosylation linkages confer patentability -- is in direct contradiction to Amgen's prior position, Amgen should be judicially estopped from maintaining its current argument. Amgen's argument that Roche cannot "use Dr. Lin's specification as support for its

arguments" (D.I. 867 at 16) is irrelevant to this inquiry: whether or not this statement renders the polypeptide claims invalid for ODP will be determined at trial.

Finally, Amgen's arguments with respect to Mr. Brenner's expert report and Amgen's own statements in UK proceedings are baseless. Mr. Brenner plainly said "that as of 1983, once you were given all the exons for a particular gene, getting expression of the protein was frankly routine. As I have said the exons are the template, it is all the scientist would have required to make a clone capable of producing the protein." (D.I. 803 Ex. 8 at ¶ 66). Amgen succeeded in having the court adopt this position, and Amgen should not now be permitted to change its story simply because it is faced with a new challenge.

III. CONCLUSION

Amgen's attempt to distract the Court from the simple and clear conclusion that judicial estoppel should operate to protect the sanctity of the judicial system and preclude Amgen from playing fast and loose with the courts must fail. Amgen's 18-page opposition to Roche's motion is riddled with irrelevant arguments and "evidence" that have nothing to do with Roche's motion. Accordingly, for the reasons stated above, along with those set forth in Roche's Opening Memorandum of Law (D.I. 802), Amgen should be judicially estopped from making the following arguments, in contradiction to prior assertions successfully asserted in other judicial proceedings:

(1) that the Lin process claims of the '868 and '698 patents are not obvious over the '008 patent claims;

(2) that the use of mammalian host cells for expression of EPO confers patentability;

(3) that isolation of the EPO glycoprotein product from mammalian host cell expression confers patentability;

(4) that purported differences in glycosylation linkages confers patentability to the asserted claims of the patents-in-suit; and

(5) that the production of a biologically active protein was an "unexpected result."

Dated: August 30, 2007
Boston, Massachusetts

Respectfully submitted,

F. HOFFMANN-LA ROCHE LTD,
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